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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/580,646

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Ivo Glynne Gut

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EXAMINER

CALAMITA, HEATHER

ART UNIT

PAPER NUMBER

1637

MAIL DATE

DELIVERY MODE

10/15/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/580,646	Applicant(s) GUT ET AL.	
	Examiner HEATHER G. CALAMITA	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7,9,13 and 18-21 is/are pending in the application.
- 4a) Of the above claim(s) 18 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-7 and 19-21 is/are allowed.
- 6) ☒ Claim(s) 9 and 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/25/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. To clarify the record the Restriction requirement mailed May 27, 2009, contained two typographical errors. The Groups in the restrictions referred to the correct claims, however the inventions were not correctly characterized. The invention of Group I (claims 1-17 and 19-21) is drawn to a method of HLA typing. The invention of Group II (claim 18) is drawn to a kit for use in HLA typing.

2. Applicants' election with traverse of Group I (claims 1-17 and 19-21) and the species of HLA-A and the subspecies of HLA-A in the reply filed on July 27, 2009, is acknowledged. The traversal is on the ground(s) that a special technical feature exists. This is not found persuasive because as outlined in the requirement mailed May 27, 2009, there is no special technical feature because the components disclosed in the kit are known in the prior art.

The requirement is still deemed proper and is therefore made ***FINAL***.

Status of Application, Amendments, and/or Claims

3. Claims 1-7, 9, 13 and 18-21 are currently pending. Claim 18 is withdrawn as being directed to non-elected subject matter. Claims 1-7, 9, 13 and 19-21 are under examination.

Information Disclosure Statement

4. The information disclosure statement filed May 25, 2006, fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has

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not been considered. The lined through references have not been considered because no copy of the reference was provided.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 9 and 13 both depend from claim 1. Claim 1 is drawn to a method of HLA-A typing to generate subgroups A to O by determination of DNA sequence elements on both parental alleles at a set of multiple positions in the HLA-A gene. The set *consists of* 10 positions. Claim 9 requires 9 additional positions and claim 13 requires 25 additional positions. Claims 9 and 13 do not properly depend from claim 1 because claim 1 uses the language of *consists of* when defining the set. The language allows for only the 10 positions recited in claim 1 and not for the additional positions recited in claims 9 and 13.

Allowable Subject Matter

6. Claims 1-7 and 19-21 are allowed. The closest prior art is Warrell et al. (Analytical Chemistry vol. 72:5233-5238 2000) and Rozemuller ("Reference panels for sequence based typing: Selection criteria for HLA-A and HLA-B", Technical Manual International Histocompatibility Working Group, 2000). Warrell et al. teach a method for HLA typing by mass spectrometry. Warrell et al. use primer oligomer base extension combined with matrix-assisted laser desorption/ionization time of flight mass spectrometry to characterize HLA polymorphisms in both parental alleles. Rozemuller teach the polymorphic positions in HLA-A and HLA-B. However, even though HLA typing is well known in the

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art and the polymorphic positions are disclosed by Rozemuller it is not obvious to use the specific combinations of positions recited for the typing of HLA-A. There is no reason or motivation provided for a skilled artisan to choose one specific subset of 10 positions over any other specific subset of 10 positions.

Correspondence

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Heather G. Calamita whose telephone number is 571.272.2876 and whose e-mail address is heather.calamita@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner can normally be reached on Monday through Thursday, 7:00 AM to 5:30 PM.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at 571.272.0782.

Papers related to this application may be faxed to Group 1637 via the PTO Fax Center using the fax number 571.273.8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to 571.272.0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Heather G. Calamita/
Examiner, Art Unit 1637